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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,367	12/15/1998	DAVID BAUNOCH	98.714	8537

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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/212,367

Applicant(s)

BAUNOCH ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 23-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 23-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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## DETAILED ACTION

### *Compact Disc Submission*

1. Portions of this application are contained on compact disc(s). When portions of an application are contained on a compact disc, the paper portion of the specification must identify the compact disc(s) and **list the files including name, file size, and creation date on each of the compact discs**. See 37 CFR 1.52(e). Compact disc labeled "METHOD AND APPARATUS FOR AUTOMATED REPROCESSING TISSUE SAMPLE" is not identified in the paper portion of the specification with **a listing of all of the files contained on the disc**. **Applicant is required to amend the specification to identify each disc and the files contained on each disc including the file name, file size, and file creation date.**

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 and 23-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 23, the recitation of the "conduits that connect the chamber to liquid containing containers" is indefinite because for the following reasons. First it is not clear if the recited "liquid containing container" are the same as the ones recited later in the claim or

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different containers. Also, it is not clear how these conduits structurally cooperate with the fluid flow selector and containers which are listed as containing clearant, dehydrant, etc.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (EP 0 508 568).

The reference of Muller et al. discloses an apparatus which is capable of reprocessing a specimen from an infiltrating medium to an aqueous fluid which includes a processing chamber (112); means for regulating flow of fluid (120,129); pressure regulator for regulating pressure of the processing chamber (257,259,232); temperature regulator (117); containers (R1-R11) for holding a series of any known processing reagents; and a computer control system (276,286) which includes a processor and memory (See column 50, lines 11-25, which discloses a microcomputer).

While the specific examples of the system do not include the sequential reprocessing as recited in instant claim 1, the disclosure of Muller et al. discusses a known process that can be performed by the disclosed system. Paraffin treated tissue sections are heated then contacted with xylene (clearant agent), then contacted with ethanol (dehydrant agent) and then contacted with aqueous hydrogen peroxide and saline (aqueous fluid) (See page 8).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to control the disclosed system of the primary reference so as to perform the known reprocessing by sequential control of reservoirs containing the required reagents to reprocess the samples as suggested by the reference of Muller et al. Regulation of temperature, pressure and flow would have been obvious to one of ordinary skill in the art while providing the required contacting conditions between the tissue sample and reagent while maintaining the contacting efficiency of the system.

The claims further differ by reciting the presence of separately valved infiltrating fluid.

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The reference of Kinney et al. discloses an automated processing system which is similar to that of Muller et al. In addition to the reagents suggested by the reference of Muller et al., the reference of Kinney et al. discloses the use of separately provided paraffin reservoirs (13, 14) (infiltrating fluid) which are separately controlled for flow with respect to the other treating agents.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the modified primary reference of Muller et al. such that tissue samples may also be automatically processed as suggested by Kinney et al. for the known and expected result of increasing versatility of the system of Muller et al. since the system of Muller et al. is disclosed as an improved means for accomplishing the sequential, multi-step, controlled processing of a slide surface mounted material.

Note the controller of Muller et al. is capable of controlling the fluid flow selector (129) to connect any of the containers to the processing chamber in any sequence.

With respect to claim 2, the reference of Muller et al. also discloses the use of a rotary valve (129).

***Allowable Subject Matter***

8. Claims 5 and 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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9. Claims 23-32 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

10. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 5 and 6, while the prior art of record discloses the use of purge dehydrant and/or purge clearant, the prior art of record fails to teach or fairly suggest a processor which controls the fluid flow selector so as to sequentially connect the processing chamber in a processing order which includes the container of clearing agent, the container of purge dehydrant, the container of dehydrant and then the container of aqueous solution to reprocess a specimen held in the chamber.

With respect to claims 23-32, while the prior art of record discloses the use of purge (contaminated) dehydrant and/or purge (contaminated) clearant, the prior art of record fails to teach or fairly suggest a processor which controls the fluid flow selector so as to sequentially connect the processing chamber in a processing order which includes the container of clearing agent, the container of contaminated dehydrant, the container of dehydrant and then the container of aqueous solution to reprocess a specimen held in the chamber.

### *Response to Arguments*

11. Applicant's arguments filed 18 Oct. 2002 have been fully considered but they are not persuasive.

Applicants argue that the combination of the references of Muller et al. and Kinney et al. does not teach or suggest the instant claimed invention.

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Applicants state that the claims as now amended which states "a control device having a processor and memory device, the processor controlling . . . the fluid flow selector to connect any of the containers to the processing chamber in any sequence" "thereby automatically and sequentially processing and reprocessing the specimen".

In response, the instant claims merely state that the controller can connect any of the containers to the processing chamber in any sequence. The system of the instant invention employs a rotary valve connected to a plurality of containers. The prior art also discloses the use of a plurality of containers and a rotary valve. As a result, the structure of the prior art is capable of connecting any of the containers to the processing chamber in any sequence. The instant claims do not further refine the act of processing or reprocessing in terms of specific steps which define over the prior art of record.

With respect to the declaration filed under 37 CFR 1.132 filed 29 Jan. 2002, see the Examiner's comments in section (9) of the office action dated 17 April 2002.

In response to Applicants' second argument, both the references of Muller et al. and Kinney et al. are drawn to automated processes of reprocessing or processing.

In response to Applicants' third argument, which is drawn only to the deficiencies of the reference of Kinney et al., one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

### *Conclusion*



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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

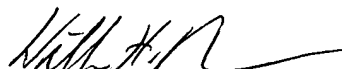
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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William H. Beisner

Primary Examiner

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WHB

March 23, 2003